REMARKS

In view of the preceding amendments and the following remarks, Applicants respectfully request the Examiner to reconsider the patent application identified above and withdraw the present rejection. Claims 1-18 are pending in the present application, and with this amendment Claims 1-16 have been withdrawn from consideration in response to a restriction requirement, but may be submitted for further prosecution in a later continuing application. Claims 17 and 18 are currently rejected.

35 U.S.C. §121:

Claims 1-18 are subject to a restriction requirement. The Examiner objected that the present application contains claims directed to the following distinct groups of the claimed invention:

Group I	Claims 1-16	medical device
Group II	Claims 17, 18	method of treatment

Applicants confirm the provisional election of Group II, Claims 17 and 18, made in a telephone conversation with the Examiner.

35 U.S.C. §103:

The Examiner rejected Claims 17 and 18 under 35 U.S.C. §103(a) as being unpatentable over Wallace et al. (US 2002/0143348) in view of Pinchuk et al. (US 2002/0207330). Applicants respectfully submit that the cited references fail to teach or suggest the present invention, as recited in the Claims. For example, Claims 17 and 18 include the following limitations, among others:

> a *barrier* exhibiting the characteristic of normally *preventing a reaction between the bioactive agent and a bodily fluid* and of *exposing* a portion of said bioactive agent *when an external agent is applied to said barrier;*
>
> * * *
>
> applying said *external agent* through the catheter and into the blood vessel *to thereby activate said barrier to expose said bioactive agent to*

> *bodily tissue* to thereby cause a reaction between the bioactive agent and the bodily tissue;

(Application, Claim 17. Emphasis added.)

> a *barrier* which exhibits the characteristic of normally *inhibiting a reaction between said bioactive surface of said medical device and bodily tissue;*
>
> * * *
>
> applying an *external agent* through the catheter to a selected site *to thereby activate said barrier and thus expose said bioactive surface to bodily tissue* to thereby cause a reaction between the bioactive surface and the bodily tissue.

(Application, Claim 18. Emphasis added.)

For example, the Wallace reference describes "embolic assemblies that can be *reinforced in situ.*" (Abstract. Emphasis added.) The Wallace reference does mention "partially solvating polymeric materials of the implantable device," but describes that they will later "re-solidify":

> The liquid agent is capable of *transforming into a solid form* for example, slowly over time or by reaction with an agent already present in the luminal portion of the device. In addition, assemblies and methods are described comprising an implantable device and a liquid agent, wherein the liquid agent is capable of solvating polymeric material of the device. *By partially solvating polymeric materials of the implantable device, when these polymeric materials re-solidify* the implantable devices can be bonded to themselves and/or to other implantable devices.

(Wallace, paragraph 23. Emphasis added.)

> ...the implantable device comprises a polymeric material capable of controllable being *at least partially solvated (or plasticized) and, subsequently, re-solidifying.* In these embodiments, the liquid agent comprises a substance that acts to at least partially solvate (or dissolve) the implantable device such that the device can then be bonded to itself (e.g., the individual winds of a coil) or bonded to another implantable device which has been similarly solvated.

(Wallace, paragraph 40. Emphasis added.)

The Examiner concedes that "Wallace does not, however specifically teach a bioactive agent disposed between the support member and the barrier nor does he teach the polymer is specifically a barrier." Applicants agree completely.

Regarding the Pinchuk et al. reference, the Examiner states that it "does teach a barrier layer of polymers", and quotes Pinchuk:

> In some instances, it may be desirable to temporarily enclose the therapeutic-agent-loaded copolymer to prevent release before the medical device reaches its ultimate placement site.

(Pinchuk, paragraph 183.)

> It also may be useful to coat the copolymer of the present invention (which may or may not contain a therapeutic agent) with a layer with an additional polymer layer (which may or may not contain a therapeutic agent). This layer may serve, for example, as a boundary layer to retard diffusion of the therapeutic agent and prevent a burst phenomenon whereby much of the agent is released immediately upon exposure of the device or device portion to the implant site.

(Pinchuk, paragraph 204.)

One of the differences is that the barrier of the present invention does not release the bioactive agent until the external agent is applied. In other words, the prior art includes embolic devices having an outer coating which automatically dissolves when in contact with blood flow, without waiting for a specific external activating agent. As described in the "Description of the Prior Art" from the present application:

> In addition, U.S. Patent No. 5,980,550, entitled, "Water-Soluble Coating For Bioactive Vasoocclusive Devices," discloses an embolic coil having an inner coating which serves as a thrombogenic agent and an *outer coating of a water soluble agent which dissolves after placement of the coil in order expose the thrombogenic inner coating* to enhance the growth of thrombus into an around the coil.
>
> *The water soluble coating prevents the thrombogenic inner coating from coming into contact with the surrounding blood until the water soluble*

> *coating is dissolved by contact with blood which is comprised largely of water.*
>
> While the vasculature occlusive device disclosed in this patent includes an agent for enhancing thrombogenicity of the device and also includes an outer coating to prevent such activity until the outer coating is dissolved by blood flow, *there is no control over when the dissolving process begins* and therefore *no control over the time in which the thrombogenic agent becomes activated.* Without such control, it is possible that thrombus can begin forming on the coil prior to the time the coil is properly placed within a vessel, or aneurysm, therefore making it very difficult if not impossible to reposition, or remove the improperly placed coil.

(Application, page 3, line 14 to page 4, line 6. Emphasis added.)

Accordingly, the present application describes the outer barrier of the present invention as requiring an "external agent" to be applied, before exposing the bioactive agent. In other words, the present invention is more stable (requiring the addition of some external agent), rather than activating immediately upon insertion into the body (which might be earlier than optimal).

Double Patenting:

The Examiner provisionally rejected Claims 17 and 18 for non-statutory obviousness-type double patenting over (i) Claims 26 and 27 of co-pending application number 10/868,152, (ii) Claims 26 and 27 of co-pending application number 10/738,473, and (iii) Claims 49 and 50 of co-pending application number 10/874,864.

The Examiner has stated that a terminal disclaimer may be used to overcome a rejection based on a ground of non-statutory double patenting, if the reference is commonly owned with the present application.

Applicants have submitted such a terminal disclaimer, disclaiming the term of any patent to issue for the present application that may extend beyond the term of any patent to issue for any of these three co-pending applications.

Applicants respectfully request the Examiner to allow the present invention.

Respectfully submitted,
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Date: February 4, 2008

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